

THE EFFECT OF SMEAR LAYER REMOVAL ON ENDODONTIC OUTCOMES

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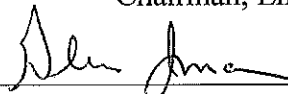
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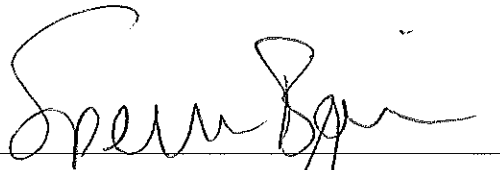


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ABSTRACT

Introduction: The biomechanical process of cleaning and shaping the root canal system creates a layer of organic and inorganic debris called the smear layer. This layer is effectively removed using a combination of ethylene-diamine-tetraacetic-acid (EDTA) and sodium hypochlorite (NaOCl). Currently, there are limited clinical outcome studies available to justify the decision to remove or retain the smear layer prior to obturation. Because of this, the practice of smear layer removal is debatable. This prospective, randomized, double-blinded clinical trial compared the endodontic outcomes of teeth in which the smear layer was purposely removed against teeth in which the smear layer remained. Furthermore, the influence of covariant factors on endodontic outcomes was analyzed. **Materials and Methods:** After initial evaluation, all subjects were randomly assigned to either one of the two irrigation protocols. A standardized treatment protocol was followed with the exception of the final irrigation regimen. Group A received 1ml/canal of 17% EDTA while Group B received 1ml/canal of 0.9% saline, each followed by 3ml/canal of 6% NaOCl as the final irrigant. Standardized radiographic and clinical evaluations were conducted no less than 12 months after treatment to determine outcomes. A power analysis determined 440 subjects will be needed for analysis. Data were analyzed using Fisher's Exact test ($\alpha=0.05$). **Results:** An interim analysis of 147 subjects revealed no significant differences between irrigation protocol groups ($p=0.183$). Additionally, the only covariate to significantly affect healed rates was the presence of a pre-operative apical lesion ($p=0.003$). **Conclusion:** Under the conditions of this *in-vivo* clinical study, smear layer removal did not affect endodontic outcomes.

INTRODUCTION

Bacteria play a major role in the development and progression of pulpal and periapical disease (1). The goal of root canal treatment is to remove diseased pulpal tissue and reduce bacteria within the canal through a thorough chemo mechanical process. During instrumentation of the canal system, a superficial smear layer containing organic and inorganic particles; namely, pulpal remnants, dentinal debris, odontoblastic processes and bacteria, are left behind on dentinal walls (2,3). This layer of debris is estimated to be 1-2 μ m thick and may become packed into the dentinal tubules up to a depth of 110 μ m creating a smear plug (4,5). Smear plugs may entrap bacteria within the tubules and potentially prevent adequate cleaning of the canal system (6).

The smear layer is tenaciously attached to the dentin wall and cannot be removed by rinsing with saline alone (7). A chemo mechanical instrumentation regimen that incorporates the chelating agent ethylenediaminetetraacetic acid (EDTA) has been shown to effectively remove the smear layer and expose dentin tubules (2,7). The literature supports using 1ml of 17% EDTA over a 1-minute exposure followed by 3ml of full strength sodium hypochlorite (NaOCl) as a final irrigation protocol prior to obturation (8). This combination effectively removes the smear layer while minimizing erosion of the dentinal walls (9). Other irrigants and techniques reported to remove the smear layer include hydrogen peroxide, citric and other weak acids, BioPure[®] MTAD[®], Qmix[®] and activated irrigation using ultrasonics and lasers. However, these methods have been found to be no more effective than the combination of EDTA and NaOCl (2,7,10-13).

The literature is inconclusive to whether the smear layer should be removed prior to obturation. Some studies suggest smear layer removal is advantageous because it

eliminates trapped bacteria (2), allows for a higher quality seal (14), and decreases bacterial leakage (15). Other studies do not recommend smear layer removal because it increases dentin permeability, creates an additional avenue for bacterial leakage (3) or disrupts the apical seal (16). Studies advocating leaving the smear layer intact have theorized its presence may prevent the initial penetration of bacteria into dentinal tubules (17). These conflicting studies may explain a 2001 survey that revealed more than 75% of dental students and nearly 70% of endodontic residents were not taught to routinely remove the smear layer. Furthermore, 50% of responding endodontists routinely removed the smear layer prior to obturation (18). A more recent 2012 survey reported 77% of endodontists routinely removed the smear layer prior to obturation (19).

To date, no *in-vivo* outcome studies have evaluated the intentional removal of the smear layer in a root canal system and its effect on healing of nonsurgical endodontic treatment in permanent teeth. This is an interim analysis of a prospective double blind randomized clinical trial investigating, 1) the effect of smear layer removal on endodontic outcomes and 2) the impact of covariate factors on outcomes.

MATERIALS AND METHODS

Patient selection. The Institutional Review Board (IRB) at the Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD approved this study. Funding was provided by WRNMMC, Bethesda, MD. The Endodontics Department at the Naval Postgraduate Dental School (NPDS) is a referral-based clinic serving an active and retired military population, their family members and other eligible beneficiaries. Prior to receiving any treatment, all patients received a comprehensive endodontic evaluation. Patients were asked to participate in this study if they were 18 years or older and had the ability to consent, were in good health (American Society of Anesthesiology health status classification I or II) and required initial NSRCT without any prior treatment and could be completed in a single visit. Additionally, all participants agreed to return for a 1-year follow-up examination. Patients with a history of periodontal disease, previously initiated or previously treated, on antibiotic therapy or presenting with an acute apical abscess were ineligible to participate. Those patients allergic to any medication or dental material used in the study, including latex or gutta percha, and subjects who reported being pregnant were not asked to participate in the study.

Treatment protocol. Once enrolled, subjects were randomly assigned to one of two treatment groups (A or B). Two pre-operative periapical radiographs were taken, one straight on and one angled. Medical conditions, clinical symptoms and diagnostic and treatment information were collected on standardized data collection forms. All treatment was provided by NPDS endodontic residents using dental operating microscopes and verified by endodontic staff. With the exception of the test irrigant, either 17% EDTA or

0.9% sterile saline, a standardized treatment protocol was utilized for all subjects regardless of group assignment. Subjects were anesthetized and the tooth being treated was isolated with rubber dam and Oraseal[®] caulking adhesive (Ultradent Products, South Jordan, UT). Straight-line access was established using #2 round or #557 carbide burs (Henry Schein, Melville, NY) and EndoZ burs (Dentsply Maillefer, Tulsa, OK). Coronal flaring was created using #2, #3, and #4 Gates Glidden drills (SybronEndo Corporation, Orange, CA). Canal working lengths were established using a Root ZX[®] (J Morita, Irvine, CA) and confirmed radiographically. A glide path was created using 0.02 taper #10, #15, #20 FlexoFile[®] stainless steel files to working length. The canals were cleaned and shaped with 0.04 Profile (Dentsply Maillefer, Tulsa, OK) rotary files using a crown down technique to at least a master apical file size #35 with .04 taper. Recapitulation was performed with 0.02 taper #10 FlexoFiles to working length and irrigated with 6% NaOCl, delivered from a 30-gauge side vented irrigation tip between all file sizes for a total intraoperative irrigation volume not exceeding 3ml. The canals were then dried with sterile paper points (Henry Schein, Melville, NY).

In order to blind the clinician to the final irrigation protocol, the provider was handed a syringe containing one of the two irrigating solutions labeled “irrigant A” or “irrigant B”. Group A received a rinse with 17% ETDA and group B with 0.9% saline. The clinician delivered 1ml of the test irrigant 1mm short of working length over 1 minute per canal, after which identical treatment for all subjects resumed.

A final rinse of 3ml of 6% NaOCl per canal was performed and the canals were dried with sterile paper points. A System B[®] (SybronEndo, Orange, CA) plugger was selected that bound within the canal 5-7 mm short of working length. Working length was confirmed

using a 0.04 taper master gutta percha cone (Diadent, Burnaby, BC, Canada). Roth 801 sealer (Roth International LTD, Chicago, IL) was delivered into the canal using a lentulospiral (Dentsply Maillefer, Tulsa, OK). The master cone was seated to working length and the canal was obturated with gutta percha using a continuous wave technique. The canal was backfilled using an Obtura IITM (Obtura Spartan, Earth City, MO). Alcohol-soaked cotton pellets were used to clean the chamber prior to temporizing the access with a sterile cotton pellet and Fuji Triage[®] (GC America Inc., Alsip, IL) or CavitTM Temporary Filling Material (3M ESPE Dental, St Paul, MN). A post-operative radiograph was taken using a XCP[®] (Dentsply Rinn, York, PA) device with Blu-Mousse[®] (Parkell inc, Edgewood, NY) bite registration material in order to reproduce the vertical and horizontal angles of the radiograph at the follow-up appointment. The subject was instructed to return to the referring dentist for the permanent restoration.

A follow-up examination, conducted no less than 12 months following treatment, was completed. Providers reviewed health history and recorded clinical data including results from diagnostic testing on standardized follow-up data collection forms. A periapical radiograph was taken using the positioning device previously created at the treatment appointment. A pulpal and apical diagnosis was made based on diagnostic testing conducted during the follow-up exam.

Outcomes assessment. Data from the treatment and follow-up exam were utilized to determine the endodontic outcome. Subjects that were classified as “Healed” were defined as asymptomatic and absence of radiographic lesion at the time of follow-up, while “non-healed” subjects were defined as either symptomatic and/or presence of a radiographic lesion.

PAI scoring. The PAI scoring, described by Ørstavik (20), was conducted by 3 calibrated, board certified endodontists. The coronal restorations of the immediate post operative and 1-year follow-up radiographs were masked to eliminate reviewer bias. Radiographs were coded, randomized and individually projected onto a screen in a dark room. Radiographs were scored individually, and when there was disagreement, forced consensus was used. A PAI score of 1 or 2 was considered healed while a PAI score of 3, 4 or 5 was considered non-healed. All data were entered into SPSS Statistics (IBM, Armonk, NY).

Statistical analysis. To establish sample size, a power analysis was performed estimating an 80% healed rate at 12 months. In order to estimate the true healed rate to within 5 percentage points, a sample size of 440 subjects will be evaluated for significance using the fisher's exact test and logistic regression.

RESULTS

This interim analysis reports that a total of 213 subjects were enrolled in this study. 11 subjects did not complete the NSRCT at NPDS, resulting in 202 subjects who were eligible for follow-up. 175 subjects completed the follow-up examination resulting in a follow-up rate of 87%. Twenty-eight of the subjects with a completed follow-up were unable to be analyzed due to extraction of the studied tooth (n=12) or a deviation from protocol during treatment (n=16). The most common protocol deviation was completion of the NSRCT over more than a single-visit. The remaining 147 subjects were analyzed. As shown in Figure 1, 39/77 (50.6%) subjects assigned to the 17% EDTA healed while 44/70 (62.9%) subjects assigned to the 0.9% saline group healed. This difference was not statistically significant ($p = 0.183$).

Figure 2 contains a list of covariate factors that were analyzed for this interim analysis. Other factors did not have sufficient data to be analyzed. The presence of a pre-operative radiolucency was the only covariate factor that demonstrated a significant influence on healed rates. Only 40.3% of subjects with a pre-operative radiolucency healed, while 67.0% of subjects without a pre-operative radiolucency healed ($p=0.001$) (Table 1).

DISCUSSION

There is an abundance of endodontic literature regarding smear layer removal. However, the majority of published smear layer studies were completed *in vitro* and therefore data evaluating its removal on endodontic outcomes is lacking. Additionally, the published literature is inconclusive: several studies report an advantage to smear layer removal while others report possible detriment to smear layer removal. The decision to remove the smear layer is currently based on conclusions from many *in vitro* studies. *In vitro* studies in favor of smear layer removal have concluded that removing the smear layer releases trapped bacteria (2), allows for a higher quality seal (14) decreases microleakage (15), creates a medicament effect on infected dentin (21) and enhances diffusion of intracanal medicaments (22). In addition, Soares et. al. reported that the combined irrigation of EDTA and sodium hypochlorite may enhance the disruption of *E. faecalis* biofilms (23).

In contrast, the literature is also abundant with studies supporting leaving the smear layer intact. *In vitro* studies supporting smear layer retention reported increased apical microleakage with smear layer removal (16) and increased dentinal erosion with the combined use of EDTA and sodium hypochlorite (24). Other studies have suggested that removing the smear layer may increase bacterial leakage (3) and similarly, Drake et. al. found a decreased number of bacteria in dentinal tubules when the smear layer was left intact (17).

The purpose of this prospective double blind randomized clinical study was to investigate the influence of smear layer removal on endodontic outcomes during single-visit initial NSRCT. In order to minimize the effects of various clinical decisions between providers, a standardized protocol was designed prior to any subjects receiving treatment.

The protocol consisted of the exact materials and techniques to be used throughout the procedure. All endodontic providers were informed of the protocol via PowerPoint presentation prior to treating any subjects. Additionally, providers were given a printed copy of the standardized protocol and instructed to follow it exactly throughout treatment.

This interim analysis determined that removing the smear layer using a combination of 17% EDTA and 6% NaOCl did not lead to improved healed rates. The results of this study agree with a prospective outcomes study which reported the use of 17% EDTA had no significant effect on the outcome of initial NSRCT (25). However, this comparison may not be appropriate due to significant differences in methodology. There are 2 published outcomes studies evaluating the effect of smear layer removal on primary teeth prior to pulpectomy treatment. One of them reported a significant difference in pulpectomy outcomes after removing the smear layer (26), and the other reported no significant difference (27). There are differences between the methodology of these studies and that of the current study. These differences include: primary vs. permanent teeth, citric acid vs. EDTA as the smear layer removal irrigant, multi-visit vs. single visit treatment, use of an intra canal medicament vs. no medicament, obturation with zinc-oxide eugenol vs. gutta percha, and multi-year vs. one year follow-up. The differences in methodologies between these previous studies and the current study make it difficult for comparisons.

There are several possible reasons why no difference in outcomes between the groups was discovered. Kakehashi et. al. demonstrated that intracanal bacteria causes apical pathosis (1). Clegg and others reported 6% NaOCl was effective in eradicating both planktonic bacteria and bacteria trapped within the tenacious biofilm environment (28). Additionally, Ferrer-Luque and others reports rotary instrumentation significantly reduced bacterial load

independent of either distilled water or NaOCl (29). Therefore, the reduction of bacterial load as a result of using both 6% NaOCl and rotary instrumentation in all cases in this study may overshadow any effect resulting from removal of the smear layer.

Another reason smear layer removal may not affect endodontic outcomes is due to a study by Zhao and others that reported 35-56% of the canal surface remains untouched during mechanical instrumentation (30). Therefore, a smear layer would not be created on these surfaces. This lends support to the current study's findings that removing the smear layer may not be significant in outcomes.

The secondary objective of this study was to evaluate the influence of covariate factors on endodontic outcomes. The only covariate factor found to have a significant impact on healing was the presence of a pre-operative radiographic lesion. This finding agrees with several previously published outcome studies (25, 31-32).

The limitations of this interim analysis include sample size, length of follow up and the use of strict criteria during outcomes assessment. A power analysis was completed prior to protocol approval in order to determine sample size. This analysis was completed assuming an 80% healed rate based on a previously published outcome study (25). For this interim analysis, the sample size (213 enrolled subjects) is well below the sample size needed to have sufficient power (440) and therefore the results of this study could potentially change as more subjects are enrolled and analyzed.

The length of follow up in this study was set at 12 months. Ørstavik reported that after 1 year approximately 90% of teeth that will eventually heal show signs of healing (33). Additionally, considering the transient military population in the present study, it was justified to complete a 1-year follow-up, since many subjects would potentially have moved

after longer follow-up periods. Based on published endodontic literature we would expect longer follow-up times to result in increased healed rates (34).

The overall healed rate in the current study is slightly lower than previously published outcome studies due to the use of strict criteria during PAI scoring. Other outcomes studies use a scale to evaluate healing lesions (25, 34), whereas in the current study, teeth were classified as either “healed” or “non-healed” based on the combination of the clinical examination and radiographic PAI score. A recent study compared the PAI scoring system with the Strindberg system and probability index scoring systems and found the dichotomization of the PAI and the probability index provided higher intra- and inter-observer agreement values in the radiologic assessment of periapical health (35).

CONCLUSION

The interim analysis of this prospective double blind randomized clinical trial reveals there is no significant difference in endodontic outcomes after intentionally removing the smear layer during single-visit initial non-surgical root canal treatment in permanent teeth. Additionally, the presence of a pre-operative radiographic lesion was the only covariate factor determined to impact endodontic outcome.

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The authors deny any conflicts of interest related to this study.

FIGURE LEGEND

Figure 1: Chart demonstrating the healed rates of two irrigation protocols.

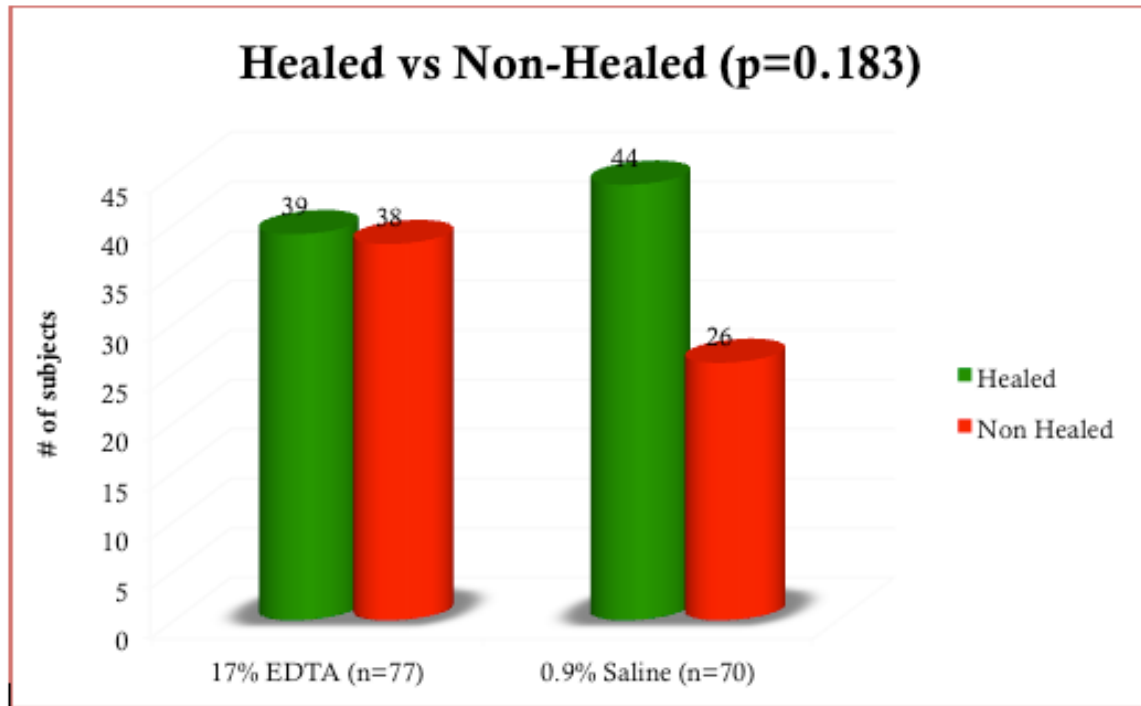


Figure 2: A list of covariate factors with sufficient data to analyze

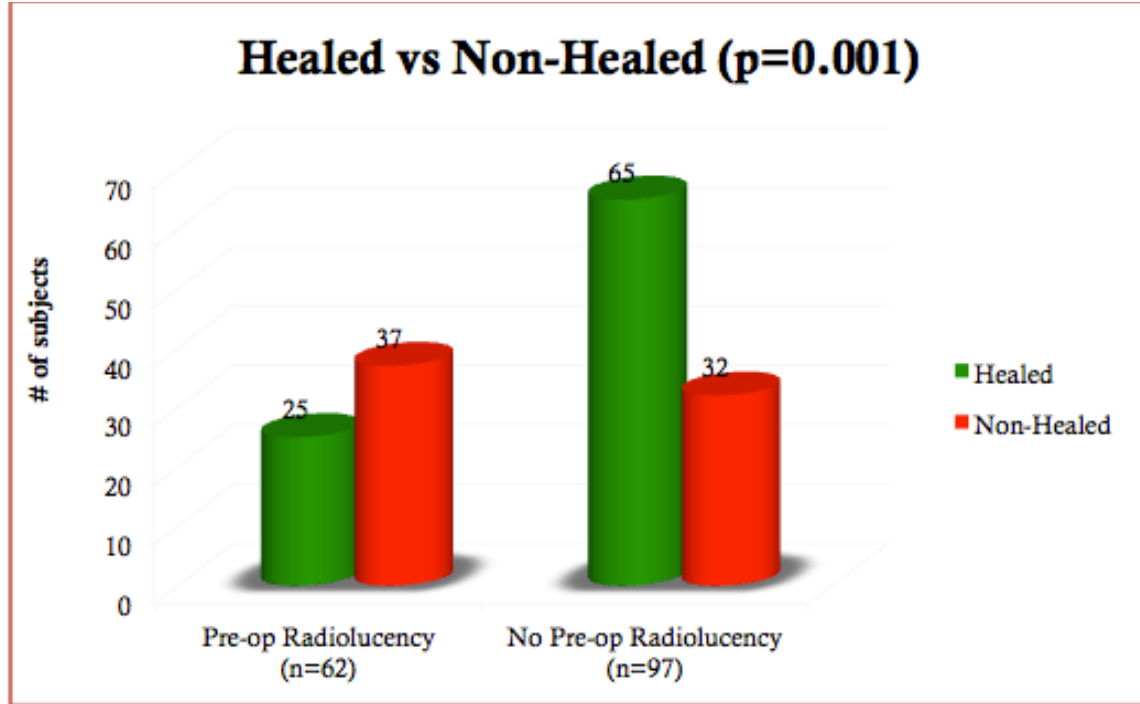


Table 1: Chart demonstrating significantly better healed rates of subjects without a pre-operative radiolucency.

Covariate Factors Evaluated		
Gender	History of external resorption	Pre-op pulpal diagnosis
Tooth position	History of bleaching	Pre-op apical diagnosis
Tooth type	History of internal resorption	Patency
Pre-op/Post-op diabetes	Pre-op/Post-op post	Procedural complications
Pre-op/Post-op HTN	Pre-op/Post-op caries	Intra orifice barrier
Pre-op/Post-op smoker	Pre-op/Post-op cold sensitivity	Number of treatment sessions
Pre-op/Post-op coronary heart disease	Pre-op/Post-op mobility	Obturation fill length
Pre-op/Post-op pain	Pre-op/Post-op bleeding on probing	Post treatment apical diagnosis
Pre-op/Post-op EPT results	Pre-op/Post-op restoration	Post treatment pulpal diagnosis
Pre-op/Post-op palpation	Pre-op/Post-op probing depths	Time lapsed between initial treatment and permanent restoration
Pre-op/Post-op percussion	Pre-op/Post-op open margin	
Pre-op/Post-op sinus tract	Pre-op/Post-op lamina dura	Follow-up apical diagnosis
Pre-op/Post-op swelling	Presence of pre-op radiolucency	
History of ortho treatment		

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